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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 673,779	01 02 2001	Gysbert Johan Jansen	80541	4107

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 12 28 2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,779

Applicant(s)

JANSEN ET AL.

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

1) ☐ Notice of Draftsperson's Patent Drawing Review (PDR) Form3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25) ☐ Notice of Informal Patent Application (PTO-101)6) ☐ Other

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DETAILED ACTION

Sequence Notes

1. The CRF copy of the Sequence Listing filed in this application complies with the requirements of 37 CFR 1.821-1.825 and has been entered.

Information Disclosure Statement

2. The information disclosure statement filed in this application on 11/16/00 fails to include a concise statement of the relevance of the following non-English language reference listed, as required under 37 CFR § 1.98(a)(3): 2659981. The above item of information has not been considered by the examiner. The other items of information that are otherwise in compliance with the provisions of 37 CFR §1.97-1.98 have been considered by the examiner.

Specification

3. The disclosure is objected to because of the following informalities:

A) The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 1. Field of the Invention.
 2. Description of the Related Art including information disclosed under 37

CFR 1.97-1.98

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- (g) **Brief Description of the Several Views of the Drawing(s).**
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

B) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 19). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

C) The specification is illegible due to text at the top of the page. The proper margins (at least 2 inches is recommended) should be left at the top of each page of the specification to enable legibility of the application. Corrected copies of the specified pages are required.

D) Claim 11, recites "a method", which could be amended to recite "A method".

E) Claim 26 is objected to because claim 26 does not properly depend from claims 1-23 since a claim to a product can not depend from a method of using a product (SEE MPEP 608.01(n)).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A) Claims 1-23 are indefinite over the recitation of "a bacterium suspected of being present in a sample" because it is not clear as to how one determines "a bacterium suspected of being present in a sample".

B) Claims 1-23 are indefinite because the claims do not recite a final process step which clearly relates back to the preamble. The preamble states that the method is for determining a bacterium suspected of being present in a sample, but the final process step is testing a sample with a probe according to an in situ hybridization protocol selected on the basis of the outcome of a gram staining. Therefore, it is unclear as to whether the claim is intended to be limited to a method of for determining a bacterium suspected of being present in a sample or a method of testing a sample with a probe according to an in situ hybridization protocol selected on the basis of the outcome of a gram staining.

C) Claims 1-23 are indefinite because it is not clear as to how one determines a bacterium suspected of being present in a sample by simply a) testing said sample by Gram-staining; and 2) testing said sample with a probe according to an in situ hybridization protocol selected on the basis of the outcome of said gram staining. (i.e. applicant should add method steps that clearly point out and distinctly claim the instant invention).

D) Claims 3, 7, 15, 19, and 24-25 are indefinite over the recitation of "preferably". It is unclear whether the limitation following the term "preferably" is part of the claimed invention. "Description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences lead to confusion over the intended scope of a claim." MPEP 2173.05(d).

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E) Claims 4-21 are indefinite because it is not clear as to how these claims are further limiting, as the results of the Gram stain would indicate the presence of a Gram-negative (or Gram-positive) bacteria, and determine the rod or coccus character of said bacterium.

F) Claims 5-7, 13-15, 17-19, and 25 are indefinite due to the improper expression of alternative limitations (i.e. "selected from the group of probes"). Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B, and C." (MPEP 2173.05(d)).

G) Claims 7, 15, 19, and 25 are indefinite over the recitation of "probes is having not more than five, preferably no more than two mismatches with a probe" because it is not clear as to which probe is being referred to and it is not clear which mismatches correspond to which probe. Furthermore, it is not clear as to which probes can contain mismatches and what those mismatches might be.

H) Claims 11-19 are indefinite over the recitations of "chain-like" and "clump-like" character, because it is not clear what is meant by these recitations, and furthermore these recitations are not defined in the specification.

I) Claim 22 is indefinite and vague because the claim is written in the passive tense. Method claims should recite positive, active process steps (see *Ex parte Erlich* 3 USPQ 2d 1011). This rejection may be overcome by amending the claims to recite the active tense (e.g. "further comprising, binding bacteria present...; fixing..."). Furthermore, Applicant should include

...the step of ... to perform said claim

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J) Claim 23 is indefinite over the recitation of "probe selected for its reactivity with one or a group of bacterial genera or species having congruent susceptibility to antibiotic treatment" because it is not clear as to what is meant by this recitation. (i.e. it is not clear as to how a probe is selected by its reactivity, and the recitation of "having congruent susceptibility to antibiotic treatment" is not clear as this recitation is not defined in the specification.

K) Claim 24 is indefinite over the recitation of "having congruent susceptibility to antibiotic treatment" because it is not clear as to what is meant by this recitation, and furthermore, this recitation is not defined in the specification. Furthermore, it is not clear as to what a "probe designed to hybridize specifically with a nucleic acid in bacteria with congruent susceptibility or resistance to antibiotics" actually consists of. (i.e. it is not clear as to whether this probe should have a specific structure, whether it should hybridize to a specific nucleic acid sequence in a specific bacteria, etc.).

L) Claim 26 is indefinite because it is not clear as to exactly what components make up the diagnostic kit.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen (GenEmbl Accession No. X91531).

Pedersen teaches a probe that has no more than five, preferably no more than two mismatches with the probe of SEQ ID NO: 1. Specifically, Pedersen teaches GenEmbl Accession No. X91531, which is a probe designed to hybridize specifically with nucleic acid in bacteria, and is 100% identical (i.e. having zero mismatches) with SEQ ID NO: 1.

8. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kita-Tsukamoto (GenEmbl Accession No. D11293).

Kita-Tsukamoto teaches a probe that has no more than five, preferably no more than two mismatches with the probe of SEQ ID NO: 2. Specifically, Kita-Tsukamoto teaches GenEmbl Accession No. D11293, which is a probe designed to hybridize specifically with nucleic acid in bacteria, and is 100% identical (i.e. having zero mismatches) with SEQ ID NO: 2.

9. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Olins (GenEmbl Accession No. I05065).

Olins teaches a probe that has no more than five, preferably no more than two mismatches with the probe of SEQ ID NO: 3. Specifically, Olins teaches GenEmbl Accession No. I05065, which is a probe designed to hybridize specifically with nucleic acid in bacteria, and is 100% identical (i.e. having zero mismatches) with SEQ ID NO: 3.

10. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Welling et al. (GenEmbl Accession No. A59320).

Welling et al. teaches a probe that has no more than five, preferably no more than two mismatches with the probe of SEQ ID NO: 4. Specifically, Welling et al. teaches GenEmbl Accession No. A59320, which is a probe designed to hybridize specifically with nucleic acid in

11. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by SEQ ID NO: 4

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11. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Berns (DE 4325699, and N_Geneseq Accession No. Q85466)

Berns teaches a probe that has no more than five, preferably no more than two mismatches with the probe of SEQ ID NO: 5. Specifically, Berns DE 4325699 (see Figure 3, nucleotides 1180-1197), and N_Geneseq Accession No. Q85466, which is a probe designed to hybridize specifically with nucleic acid in bacteria, having no more than 5 mismatches.

12. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (GenEmbl Accession No. A32047).

Barry et al. teaches a probe that has no more than five, preferably no more than two mismatches with the probe of SEQ ID NOS: 6, 9, and 10. Specifically, Barry et al. teaches GenEmbl Accession No. A32047, which is a probe designed to hybridize specifically with nucleic acid in bacteria, and is 100% identical (i.e. having zero mismatches) with SEQ ID NOS: 6, 9, and 10.

13. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Cai (GenEmbl Accession No. X76177).

Cai teaches a probe that has no more than five, preferably no more than two mismatches with the probe of SEQ ID NO: 7. Specifically, Cai teaches GenEmbl Accession No. X76177, which is a probe designed to hybridize specifically with nucleic acid in bacteria, and is 100% identical (i.e. having zero mismatches) with SEQ ID NO: 7.

14. Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by MacLean et al. (GenEmbl Accession No. Z26896).

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MacLean et al. teaches a probe that has no more than five, preferably no more than two mismatches with the probe of SEQ ID NO: 8. Specifically, MacLean et al. teaches GenEmbl Accession No. Z26896, which is a probe designed to hybridize specifically with nucleic acid in bacteria, and is 100% identical (i.e. having zero mismatches) with SEQ ID NO: 8.

15. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Gilson et al. (USPN 5492811).

Gilson et al. teaches a kit comprising a means for detecting or identifying a bacterium. Specifically, Gilson teaches,

"A test kit for the identification of various bacterial species groupings comprises a DNA probe which can identify palindromic units specific to particular bacterial species or species groupings. Such probes are highly specific for particular species or species subgroups. Accordingly, specific identification of bacteria may be achieved." (see abstract).

Conclusion

16. The prior art does not teach or suggest a method of identifying a bacteria in a sample by first performing a Gram-staining test on said sample, and then based on the results on the Gram-stain, and performing an in situ hybridization reaction using specific probes that can detect the bacteria in said sample. Therefore, claims 1-23 are free of the prior art, however, these claims are rejected for other reasons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

mailing address is: Alexander H. Spiegler, P.O. Box 1152, Ft. Collins, Colorado 80521. The Examiner's telephone numbers for the

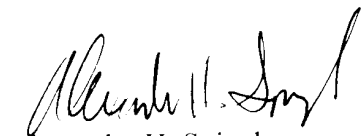
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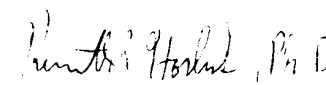
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organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alexander H. Spiegler
December 27, 2001


KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1600
12/27/01